IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: '318 PATENT INFRINGEMENT LITIGATION	)	C.A. No. 05-356-KAJ (consolidated)

NOTICE OF DEPOSITION AND SUBPOENA OF SANDOZ INC. PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 45

PLEASE TAKE NOTICE that, pursuant to Rule 45 of the Federal Rules of Civil Procedure, plaintiffs Janssen Pharmaceutica N.V., Janssen, L.P. and Synaptech, Inc. (collectively, "Janssen") will take the deposition upon oral examination of Sandoz Inc. at the offices of Esquire Deposition Services, 90 Woodbridge Center Dr., #340, Woodbridge, New Jersey 07095, beginning at 10:00 A.M. on June 14, 2006.

NOTICE IS FURTHER GIVEN THAT the deposition will be recorded stenographically through instant visual display of testimony (real-time), by certified shorthand reporter and notary public or such other person authorized to administer oaths under the laws of the United States, and shall continue from day to day until completed. This deposition will be videotaped.

NOTICE IS FURTHER GIVEN THAT pursuant to the Federal Rules of Civil Procedure, Janssen will serve upon Sandoz Inc. a Subpoena in a Civil Case. Attached hereto as Exhibit A is a true and correct copy of that Subpoena.

ASHBY & GEDDES

/s/ Tiffany Geyer Lydon

Steven J. Balick (I.D. #2114)
John G. Day (I.D. #2403)
Tiffany Geyer Lydon (I.D. #3950)
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222 Delaware Avenue, 17th Floor
P.O. Box 1150
Wilmington, DE 19899
(302) 654-1888

Attorneys for Janssen Pharmaceutica N.V., Janssen, L.P., and Synaptech, Inc.

Dated: May 26, 2006

169934.1

EXHIBIT A

A088 Subpoena in a Civil Case

Issued by the

United States District Court

District of New Jersey

IN RE: '318 PATENT INFRINGEMENT LITIGATION

SUBPOENA IN A CIVIL CASE

Case Number:[1] C.A. No. 05-356-KAJ (consolidated)
(District of Delaware)

TO: SANDOZ INC.
506 Carnegie Center, Suite 400
Princeton, NJ 08540

☐ YOU ARE COMMANDED to appear in the Unites States District court at the place, date, and time specified below to testify in the above case.

PLACE OF TESTIMONY	COURTROOM
	DATE AND TIME

☒ YOU ARE COMMANDED to appear at the place, date, and time specified below to testify at the taking of a deposition in the above case. Please See Schedule A Attached

PLACE OF DEPOSITION Recording Method: By stenographer and videotape	DATE AND TIME
Esquire Deposition Services, 90 Woodbridge Center Dr., #340, Woodbridge, NJ 07095	June 14, 2005 at 10:00 am

☐ YOU ARE COMMANDED to produce and permit inspection and copying of the following documents or objects at the place, date, and time specified below (list documents or objects):

PLACE	DATE AND TIME

☐ YOU ARE COMMANDED to permit inspection of the following premises at the date and time specified below.

PREMISES	DATE AND TIME

Any organization not a party to this suit that is subpoenaed for the taking of a deposition shall designate one or more officers, directors, or managing agents, or other persons who consent to testify on its behalf, and may set forth, for each person designated, the matters on which the person will testify. Federal Rules of Civil Procedure, 30(b)(6).

ISSUING OFFICER'S SIGNATURE AND TITLE (INDICATE IF ATTORNEY FOR PLAINTIFF OR DEFENDANT)	DATE AND TIME
Attorney for Plaintiffs Janssen Pharmaceutica N.V., Janssen L.P., and Synaptech, Inc.	May 26, 2006
ISSUING OFFICER'S NAME, ADDRESS AND PHONE NUMBER Tiffany Geyer Lydon, Ashby & Geddes 222 Delaware Avenue, 17th Floor Wilmington, DE 19899 Tel: 302-654-1888	

(See Rule 45, Federal Rules of Civil Procedure, Parts C&D on next page)

[1] If action is pending in district other than district of issuance, state district under case number.

PROOF OF SERVICE

DATE PLACE

SERVED

SERVED ON (PRINT NAME) MANNER OF SERVICE

SERVED BY (PRINT NAME) TITLE

DECLARATION OF SERVER

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Proof of Service is true and correct.

Executed on _____
DATE

_____
SIGNATURE OF SERVER

_____
ADDRESS OF SERVER

Rule 45, Federal Rules of Civil Procedure, Parts C&D

(c) PROTECTION OF PERSONS SUBJECT TO SUBPOENAS.

(1) A party or an attorney responsible for the issuance and service of a subpoena shall take reasonable steps to avoid imposing undue burden or expense on a person subject to that subpoena. The court on behalf of which the subpoena was issued shall enforce this duty and impose upon the party or attorney in breach of this duty an appropriate sanction which may include, but is not limited to, lost earnings and reasonable attorney's fee.

(2)(A) A person commanded to produce and permit inspection and copying of designated books, papers, documents or tangible things, or inspection of premises need not appear in person at the place of production or inspection unless commanded to appear for deposition, hearing or trial.

(2)(B) Subject to paragraph (d)(2) of this rule, a person commanded to produce and permit inspection and copying may, within 14 days after service of subpoena or before the time specified for compliance if such time is less than 14 days after service, serve upon the party or attorney designated in the subpoena written objection to inspection or copying of any or all of the designated materials or of the premises. If objection is made, the party serving the subpoena shall not be entitled to inspect and copy materials or inspect the premises except pursuant to an order of the court by which the subpoena was issued. If objection has been made, the party serving the subpoena may, upon notice to the person commanded to produce, move at any time for an order to compel the production. Such an order to comply production shall protect any person who is not a party or an officer of a party from significant expense resulting from the inspection and copying commanded.

(3) (A) On timely motion, the court by which a subpoena was issued shall quash or modify the subpoena if it

(i) fails to allow reasonable time for compliance,

(ii) requires a person who is not a party or an officer of a party to travel to a place more than 100 miles from the place where that person resides, is employed or regularly transacts business in person, except that, subject to the provisions of clause (c)(3)(B)(iii) of this rule, such a person may in order to attend trial be commanded to travel from any such place within the state in which the trial is held, or

(iii) requires disclosure of privileged or other protected matter and no exception or waiver applies, or

(iv) subjects a person to undue burden

(3)(B) If a subpoena

(i) requires disclosure of a trade secret or other confidential research, development, or commercial information, or

(ii) requires disclosure of an unretained expert's opinion or information not describing specific events or occurrences in dispute and resulting from the expert's study made not at the request of any party, or

(iii) requires a person who is not a party or an officer of a party to incur substantial expense to travel more than 100 miles to attend trial, the court may, to protect a person subject to or affected by the subpoena, quash or modify the subpoena, or, if the party in who behalf the subpoena is issued shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship and assures that the person to whom the subpoena is addressed will be reasonably compensated, the court may order appearance or production only upon specified conditions.

(d) DUTIES IN RESPONDING TO SUBPOENA.

(1) A person responding to a subpoena to produce documents shall produce them as they are kept in the usual course of business or shall organize and label them to correspond with the categories in the demand.

(2) When information subject to a subpoena is withheld on a claim that it is privileged or subject to protection as trial preparation materials, the claim shall be made expressly and shall be supported by a description of the nature of the documents, communications, or things not produced that is sufficient to enable the demanding party to contest the claim.

SCHEDULE A

DEFINITIONS

1. As used herein, "the '318 patent" shall mean United States Patent No. 4,663,318.

2. As used herein, "ANDA" shall mean Abbreviated New Drug Application.

3. As used herein, "Plaintiffs" refers to Janssen Pharmaceutica N.V., Janssen, L.P. and Synaptech, Inc., either individually or collectively.

4. As used herein, "You," "Your," or "Yours," shall mean Sandoz Inc., and Sandoz Inc.'s corporate predecessors and past or present subsidiaries including Eon Labs, affiliates, divisions, departments, officers, directors, principals, agents, employees and any individuals or entities that at any time have acted or purported to act on behalf of Sandoz Inc. or its successors.

TOPICS

1. The notice You sent to Plaintiffs on May 11, 2005, attached hereto as Exhibit 1.

2. Your patent certification regarding the '318 patent in connection with ANDA No. 77-589.

3. The notice You sent to Plaintiffs on May 12, 2005, attached hereto as Exhibit 2.

4. Your patent certification regarding the '318 patent in connection with ANDA No. 77-607.

EXHIBIT 1

SANDOZ

Beth Brannan
Director,
Regulatory Affairs

Sandoz Inc
2555 W Midway Blvd.
Broomfield, CO 80038

Tel: 303-438-4237 (Direct)
Fax: 303-438-4600

May 11, 2005

BY CERTIFIED MAIL – RETURN RECEIPT REQUESTED

Janssen Pharmaceutica
1125 Trento-Harbourton Road
Titusville, New Jersey 08560

BY EXPRESS MAIL

Janssen Pharmaceutica N.V.
Turnhoutseweg 30
B-2340 Beerse Country, BELGIUM

Re: NOTICE OF PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. ("Sandoz") of 506 Carnegie Center, Suite 400, Princeton, NJ 08540, U.S.A., hereby gives notice to Janssen Pharmaceutica ("Janssen"), the patent owner and/or its representative, that the FDA has received an Abbreviated New Drug Application ("ANDA") for Reminyl® brand galantamine hydrobromide 4 mg, 8 mg, and 12 mg tablets ("the Sandoz Products"), which contains data from bioequivalence and/or bioavailability studies.

The FDA has assigned the Sandoz ANDA the number 77-589.

Sandoz, by submitting this ANDA, seeks to obtain approval to engage in commercial manufacture, use and sale of the Sandoz Products prior to the expiration of the following U.S. patents, which is listed in Approved Drug Products as having the indicated expiration dates:

U.S. Patent No.	Patent Owner	Patent Expiry	Pediatric Exclusivity Expiry
6,099,863	Janssen Pharmaceutica N.V.	Jun. 6, 2017	n/a
6,358,527	Janssen Pharmaceutica N.V.	Jun. 6, 2017	n/a

The purpose of this communication is to provide the notice and information required by 21 U.S.C. § 355(j)(2)(B)(i) and/or (ii) (Sections 505(j)(2)(B)(i) and/or (ii) of the Food, Drug and Cosmetics Act) and to inform you that the Sandoz ANDA contains certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), which assert that the claims of said U.S. Patent Nos. 6,099,863 and 6,358,527 will not be infringed by the manufacture, use or sale of the Sandoz Products.

SANDOZ

Sandoz Inc
2555 W Midway Blvd.
Broomfield, CO 80038

Tel: 303-438-4237 (Direct)
Fax: 303-438-4600

A detailed statement of the factual and legal basis for Sandoz' opinion that U.S. Patent Nos. 6,099,863 and 6,358,527 will not be infringed by the manufacture, use or sale of the Sandoz Products is appended hereto. An Offer of Confidential Access to relevant sections of the Sandoz ANDA pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III) is appended hereto.

If you have any inquiries concerning this notice, please contact Eric Pomerantz, the Sandoz General Counsel, at the following address: 506 Carnegie Center, Suite 400, Princeton, NJ 08540.

Very truly yours,

Beth Brannan
Regulatory Affairs
Sandoz Inc.

Enclosures

May 11, 2005

DETAILED STATEMENT OF FACTUAL AND LEGAL BASIS FOR NON-INFRINGEMENT OF JANSSEN'S U.S. PATENT NOS. 6,099,863 AND 6,358,527

Under 21 U.S.C. §355(j)(2)(B)(i) and (ii), an Applicant for an Abbreviated New Drug Application ("ANDA") that makes the patent certification described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that a patent is invalid or will not be infringed must (a) notify the patent owner and the NDA holder of the drug claimed in the patent that an ANDA has been filed seeking approval to manufacture, use or sell the drug prior to the patent's expiration, and (b) include a detailed statement of the factual and legal basis for the Applicant's opinion that the patent is not valid or will not be infringed. This is that detailed statement and is hereby incorporated by reference into the Notice to which it is appended.

Sandoz Inc. ("Sandoz") is requesting approval for galantamine hydrobromide 4 mg, 8 mg and 12 mg tablets (the "Sandoz Products") under an ANDA that contains data from bioavailability or bioequivalence studies. Based on the following factual and legal analysis, Sandoz asserts that the Sandoz Products for which approval is requested prior to the expiration of U.S. Patent Nos. 6,099,863 and 6,358,527 will not infringe said patents. The discussion below sets forth in detail the factual and legal basis for Sandoz' position.

Since additional defenses to patent infringement may be discovered in the future, if sued for patent infringement Sandoz expressly reserves the right to assert defenses to patent infringement in addition to those set forth below.

SUMMARY

Janssen Pharmaceutica N.V. ("Janssen") is believed to be the holder of the NDA for Reminyl® Tablets, 4 mg, 8 mg and 12 mg strengths, and is believed to have caused U.S. Patent

Nos. 6,099,863 and 6,358,527 to be listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") as covering its products.

Janssen is also believed to be the beneficial owner of U.S. Patent Nos. 6,099,863 and 6,358,527, which are assigned on their faces to Janssen.

Sandoz, a Colorado corporation, wishes to obtain approval to market the Sandoz Products prior to the expiration of U.S. Patent Nos. 6,099,863 and 6,358,527 and has filed certifications under 21 U.S.C. §355(j)(2)(A)(vii)(IV) asserting that said patents are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of the Sandoz Products.

THE SANDOZ PRODUCTS

The Sandoz Products are galantamine hydrobromide tablets in 4 mg, 8 mg and 12 mg strengths and are bioequivalent to Reminyl® tablets 4 mg, 8 mg and 12 mg strengths respectively. Sandoz' tablets are constructed of a core containing 4 mg, 8 mg or 12 mg of galantamine hydrobromide in an intimate mixture with lactose monohydrate, citric acid monohydrate, talc, magnesium stearate, colloidal silicon dioxide and sodium starch glycolate, with an Opadry film coat.

SUMMARY OF THE CLAIMS OF U.S. PATENT NO. 6,099,863

The claims of U.S. Patent No. 6,099,863 ("the '863 patent") are directed to a fast dissolving galantamine hydrobromide tablet. The '863 patent has 10 claims, of which claim 1 is the only independent claim.

Claim 1 is directed to a tablet containing a therapeutically effective amount of galantamine hydrobromide (1:1) and a pharmaceutically acceptable carrier comprising a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25) as a diluent, and an insoluble or poorly soluble cross-linked polymer disintegrant.

Claim 2 is directed to a tablet according to claim 1 where the disintegrant is crospolyvidone or croscarmellose.

Claim 3 is directed to a tablet according to claim 1 where the carrier further comprises a glidant and a lubricant.

Claim 4 is directed to a tablet according to claim 3 where the glidant is colloidal anhydrous silica and the lubricant is magnesium stearate.

Claim 5 is directed to a tablet according to claim 1 that contains the following components by weight based on the total weight: from 2 to 10% galantamine hydrobromide (1:1), from 83 to 93% spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25), from 0.1 to 0.4% glidant, from 3 to 8% insoluble crosslinked polymeric disintegrant, and from 0.2 to 1% lubricant.

Claim 6 is directed to a tablet according to claim 5 comprising about 2 to 10% galantamine hydrobromide (1:1), about 83 to 93% spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25), about 0.2% colloidal anhydrous silica, about 5% crospolyvidone, and about 0.5% magnesium stearate.

Claim 7 is directed to a tablet according to claim 1 that is film coated.

Claim 8 is directed to a tablet according to claim 7 where the film coat comprises a film-forming polymer and a plasticizer.

Claim 9 is directed to a tablet according to claim 8 where the film coat weighs from about 3% to about 8% of the uncoated tablet core.

Claim 10 is directed to a process of preparing a tablet according to claim 3 including dry blending the active ingredient, the disintegrant and the optional glidant with the diluent,

optionally mixing the lubricant with the mixture, compressing the mixture in the dry state into a tablet and optionally film coating the tablet.

SUMMARY OF THE CLAIMS OF U.S. PATENT NO. 6,358,527

The claims of U.S. Patent No. 6,358,527 ("the '527 patent") are directed to galantamine hydrobromide tablets prepared by a process that includes dry blending and pressing the active ingredient and certain specified excipients, as well as to a method of treating dementia, mania or nicotine dependence by administration of the claimed tablet. The '527 patent has 6 claims, of which claims 1 and 6 are independent.

Claim 1 is directed to a method of treating dementia, mania or nicotine dependence by administering a tablet comprising a therapeutically effective amount of galantamine hydrobromide (1:1) and a pharmaceutically acceptable carrier comprising a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25) as a diluent, and an insoluble or poorly soluble cross-linked polymer disintegrant.

Claim 2 is directed to the method of claim 1 wherein the disorder is dementia.

Claim 3 is directed to the method of claim 2 wherein the disorder is Alzheimer's dementia.

Claims 4 and 5 are directed to the method of claim 1 wherein the disorder is mania and nicotine dependence, respectively.

Claim 6 is directed to a fast-dissolving galantamine hydrobromide (1:1) tablet made by dry blending the active ingredient, an insoluble or poorly soluble cross-linked polymer disintegrant and an optional glidant with a diluent comprising a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25), optionally mixing a lubricant with the

mixture, compressing the mixture in the dry state into a tablet, and optionally film coating the tablet.

BASIS FOR ASSERTING NON-INFRINGEMENT OF THE '863 AND '527 PATENTS

APPLICABLE LAW

Claim Construction

Claim construction defines the meaning of the claim language, which define the scope of the invention. *Gemstar-TV Guide Int'l, Inc. v. ITC*, 383 F.3d 1352, 1364 (Fed. Cir. 2004); *York Prods., Inc. v. Central Tractor Farm & Family Ctr.*, 99 F.3d 1568, 1572 (Fed. Cir. 1996); *Vitronics, Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). To ascertain the meaning of a claim, a court may consider the claim language, the specification, the prosecution file history and extrinsic evidence. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 390 116 S.Ct. 1384 (1996). The words of a claim are generally given their ordinary and accustomed meaning unless it appears from the specification or the file history that they were used differently by the inventor. *Intellicall, Inc. v. Phonometrics, Inc.*, 952 F.2d 1384, 1387 (Fed. Cir. 1992). Claim construction is the first step in an infringement analysis. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). The second step is to compare the properly construed claims to the allegedly infringing product. *Id.*

Noninfringement

A court will find "literal infringement" only where every limitation of a patent claim is found in the accused product or device. *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931 (Fed. Cir. 1987)(*en banc*). Claim limitations are not to be disregarded, and meaning must be given to all words in a patent claim. *See Exxon Chemical Patents, Inc. v. Lubrizol Corp.*, 64 F.3d 1553, 1557 (Fed. Cir. 1995). The court will consider whether the accused product literally

infringes that claim by evaluating whether the properly construed claims read on the product. *SRI Int'l v. Matsushita Elec. Corp.*, 775 F.2d 1107 (Fed. Cir. 1985). This determination is a question of fact. *Id.* at 1118. Dependent claims cannot be found infringed unless the claims from which they depend have been found to have been infringed. *Wahpeton Canvas Co. v. Frontier Inc.*, 870 F.2d 1546, 10 U.S.P.Q. 2d 1201, 1208 (Fed. Cir. 1989).

When a controversy is based on an ANDA filing, the infringement inquiry centers on what the ANDA applicant will likely market. *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997). Where the ANDA specifications describe a product that is well-defined for purposes of that inquiry, the specifications are dispositive in defining the product accused of infringement. *Bayer AG v. Elan Pharm. Research Group*, 212 F.3d 1241 (Fed. Cir. 2000).

Even if a product does not fall within the scope of the literal, or express, language of a patent claim, infringement nonetheless may be found if the patentee can establish that there is "equivalence" (i.e., no substantial difference) between the elements of the accused product and the claimed elements of the patented invention. *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997). To determine whether such equivalence exists, the court may inquire "whether a product is substantially the same thing used substantially the same way to achieve substantially the same result" as the claimed invention. *Graver Tank Mfg. Co. v. Linde Air Prod. Co.*, 339 U.S. 605 (1950).

Each element contained in a patent claim is deemed material to defining the scope of the patented invention, and thus the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole. *Warner-Jenkinson*, 520 U.S. at 29. The doctrine of equivalents is not a license to ignore the claim limitations. *Dolly, Inc. v. Spalding & Evenflo Cos.*, 16 F.3d 394, 398, (Fed. Cir. 1990). There is no infringement as a matter of law if a claim

limitation is totally missing from the accused device. *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1539, (Fed. Cir. 1991). When the preferred embodiment is described in the specification as the invention itself, the claims are not necessarily entitled to a scope broader than that embodiment. *Chimie v. PPG Industries, Inc.*, 402 F.3d 1371, 1379 (Fed. Cir. 2005) (*citing Modine Mfg. Co. v. United States Int'l Trade Comm'n*, 75 F.3d 1545, 1551 (Fed. Cir. 1996)).

The patentee, however, is precluded from capturing subject matter that could not have lawfully been claimed in light of the prior art. *Warner-Jenkinson*, 520 U.S. 17. In addition, the patentee is estopped from claiming equivalence to subject matter that a reasonable competitor would conclude, from the prosecution history, the applicant relinquished during prosecution to procure issuance of the patent. *Haynes Int'l, Inc. v. Jessop Steel Co.*, 8 F.3d 1573 (Fed. Cir. 1993), *modified*, 15 F.3d 1076 (Fed. Cir. 1994); *see also Litton Sys. Inc. v. Honeywell Inc.*, 140 F.3d 1449 (Fed. Cir. 1998).

Estoppel based on the prosecution history applies when the applicant surrenders subject matter in at least two ways: (1) amendment and (2) argument. *See, e.g., Canton Bio-Medical, Inc. v. Integrated Liner Technologies, Inc.*, 216 F.3d 1367 (Fed. Cir. 2000); *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473 (Fed. Cir. 1998). Arguments made by the patentee during the prosecution of the patent to distinguish the claimed invention form the prior art estops the patentee from taking a contrary position later during litigation. *Cybor Corp. v. FAS Technologies, Inc.*, 138 F.3d 1448 (Fed. Cir. 1998)(*en banc*).

No Valid Claim of the '863 or '527 Patents is Infringed by the Sandoz Products

The '863 patent was filed on December 9, 1998 as Application No. 09/202,187. The '863 patent issued to Paul Marie Victor Gills and Valentin Florent Victor De Conde on August 8, 2000, is assigned on its face to Janssen Pharmaceutica, N.V., and expires on June 6, 2017. The

'527 patent was filed on June 1, 2000 as Application No. 09/585,122, which was a continuation of the application that issued as the '863 patent. The '527 patent issued on March 19, 2002 to Paul Marie Victor Gills and Valentin Florent Victor De Conde, is assigned on its face to Janssen Pharmaceutica, N.V., and expires on June 6, 2017 due to a terminal disclaimer over the '863 patent.

Both patents share a common specification that describe, *inter alia*, a particular diluent mixture as an essential element of the invention itself. This mixture is a spray-dried mixture of lactose monohydrate (a common diluent) and microcrystalline cellulose (a disintegrant), in a 75:25 ratio, which the patents describe as essential to achieving the required dissolution profile for the claimed tablet:

> In order to obtain government approval to market a drug, one must not only show that the active ingredient has the stated activity and is safe to use, but it is also *necessary* to show that the formulation of the active ingredient will give a reproducible result in various patients. For example, in the case of solid formulations shaped as tablets, it is a *prerequisite* that the tablets disintegrate and dissolve within a particular period of time to a particular degree. In the present case, novel galanthamine hydrobromide tablets having a dissolution of at least 80% after 30 minutes (Q=80% after 30') (USP 23, <711> Dissolution, pp. 1791-1793, Apparatus 2 (paddle, 50 rpm; 500 ml purified water at 37° C.)) are provided. *Compliance with this dissolution specification is only met by using a particular diluent containing disintegrant, and a second disintegrant.*
>
> Thus the present invention relates to a tablet comprising as an active ingredient a therapeutically effective amount of galanthamine hydrobromide (1:1) and a pharmaceutically acceptable carrier, characterized in that said carrier comprises a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25) as a diluent, and a disintegrant. Said tablets have a dissolution or at least 80% after 30 minutes (Q=80% after 30') (USP 23, <711> Dissolution, pp. 1791-1793, Apparatus 2 (paddle, 50 rpm)).
>
> Initial experiments started out using either lactose anhydrous or lactose monohydrate as diluent, and either powdered cellulose or microcrystalline cellulose as disintegrant (see tablet formulations F1 and F2 in the Experimental Part). A particular problem which occurred during feeding the dry blend into the tablet press for direct compression, was segregation of the tablet excipients, thus causing the tablets to have a variable composition. In addition, the tablets formulations F1 and F2 did not comply at Stage 1 with the dissolution

specification of Q=80% after 30'. *In order to solve the perceived problems, the diluent was substituted for [sic] a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25)*, commercially available as Microcelac™.

* * *

Fast-dissolving tablets *according to the present invention* comprise by weight based on the total weight of the tablet core:

(a) from 2 to 10% galanthamine hydrobromide (1:1);

(b) *from 83 to 93% spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25)*;

* * *

('863 patent, col. 2, line 53 – col. 3, line 23, and col. 3, lines 47-5; '527 patent; col. 2, line 56 – col. 3, line 25, and col. 3, lines 48-53 (emphasis added)).

All of the claims of the '863 and '527 patents include the limitation requiring that the tablets comprise a "spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25)". This is no coincidence. In allowing the claims of the '863 patent to issue, the Examiner stated that the "particular carrier combination of a spray dried mixture of lactose monohydrate and microcrystalline cellulose (75:25) as a diluent and an insoluble or poorly soluble cross-linked polymer enables the fast disintegration of said tablet." ('863 Patent Prosecution History, March 11, 2000 Notice of Allowability.) Similarly, during the prosecution of the '527 patent, the patentees distinguished the prior art by arguing that it "would not motivate one of ordinary skill in the art to make a pharmaceutical composition wherein the pharmaceutically acceptable carrier comprises a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25) as a diluent, and an insoluble or poorly soluble cross-linked polymer disintegrant for use in treating dementia, mania or nicotine dependence, as required by the instant claims." ('527 Patent Prosecution History, March 12, 2001 Amendment.) Thus, the use of a claim limitation requiring a "spray-dried mixture of lactose monohydrate and

microcrystalline cellulose (75:25)" was central to the arguments for and allowance of the claims of the '863 and '527 patents.

The Sandoz Products do not contain a "spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25)." The Sandoz Products contain galantamine hydrobromide formulated with lactose monohydrate, citric acid monohydrate, talc, magnesium stearate, colloidal silicon dioxide, and sodium starch glycolate. The Sandoz Products do not contain microcrystalline cellulose in any form, let alone in a spray-dried mixture with lactose monohydrate in a ratio of 75:25. Additionally, the lactose monohydrate used in the Sandoz Products has not been spray-dried, nor has it been combined with any other ingredients prior to its addition to the tablet formulation. Therefore, the Sandoz Products do not literally infringe the '863 and '527 patents.

The Sandoz Products also do not infringe the '863 and '527 patents under the doctrine of equivalents. Since claim limitations cannot be ignored, no reasonable interpretation of the '863 or '527 patent claims would allow coverage of a pharmaceutical composition that does not contain microcrystalline cellulose, preformed spray-dried particles of any kind, or preformed spray-dried particles of a homogenous combination of lactose monohydrate and microcrystalline cellulose (75:25). The Sandoz Products are missing the critical spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25). This element, missing from the Sandoz Products, is essential to the function and operation of the invention claimed in the '863 and '527 patents, and its absence forecloses infringement even under the doctrine of equivalents.

The claims of the '863 and '527 patents are simply not entitled to a scope, either literally or under the doctrine of equivalents, that would encompass a tablet lacking a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25). As described, *infra*, the

specifications of both patents describe a tablet containing the spray-dried mixture not merely as a preferred embodiment, but as an integral part of the invention itself. The doctrine of equivalents cannot be used to reach a structure that lacks a feature the patent specification described as essential to the invention. *Gaus v. Conair Corp.*, 363 F.3d 1284, 1291 (Fed. Cir. 2004); *see, Scimed Life Systems v. Advanced Cardiovascular Systems, Inc.*, 242 F.3d 1337, 1340-47 (Fed. Cir. 2001) and cases cited therein.

CONCLUSION

For the reasons discussed above, Sandoz asserts that the Sandoz Products will not infringe the claims of the '863 and '527 patents.

ABBREVIATED NEW DRUG APPLICATION 77-562
OFFER OF CONFIDENTIAL ACCESS
PURSUANT TO 21 U.S.C. § 355(j)(5)(C)(i)(III)

Sandoz Inc. ("Sandoz") has provided notice to Janssen Pharma (hereinafter "Recipients"), that Sandoz submitted to the U.S. Food and Drug Administration ("FDA") Abbreviated New Drug Application 77-589 for galantamine hydrobromide 4 mg, 8 mg, and 12 mg tablets (referred to hereinafter in whole or in part as the "ANDA"), containing a Paragraph IV certification with respect to U.S. Patent Nos. 6,099,863 and 6,358,527 (the "Listed Patents"), which is listed in the FDA Publication, "Approved Drug Products with Therapeutic Equivalence Evaluations"; and

This document constitutes Sandoz' Offer of Confidential Access to that ANDA pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III) which provides:

> The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement;

and

Sandoz desires to offer to provide Recipients confidential access to the ANDA subject to restrictions as to persons entitled access to, and on the use and disposition of, the ANDA; and

This document accompanies Sandoz' Notice and Detailed Statement under 21 U.S.C. § 355(j)(2)(B) with respect to the Listed Patent;

1. Pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III), and subject to the restrictions contained in Section 2 below, Sandoz hereby provides Recipients this Offer of Confidential Access ("Offer") for the sole purpose of determining whether to bring an action referred to in 21 U.S.C. § 355(j)(5)(B)(iii) with respect to the Listed Patent.

2. This Offer is subject to the following restrictions as to persons entitled to access and the use and disposition of any information accessed:

A. **Persons Entitled to Access**: Persons entitled to access ("Authorized Evaluators") under this Offer of Confidential Access are restricted to: (i)

outside counsel engaged or employed by Recipients to represent them and the staff of such outside counsel, including paralegal, secretarial and clerical personnel who are engaged in assisting such counsel, provided that such outside counsel has been identified to Sandoz in writing; (ii) no more than two (2) in-house counsel and the staff of such in-house counsel, including paralegal, secretarial and clerical personnel who are engaged in assisting such counsel; and (iii) independent consultants and experts assisting in the evaluation of possible infringement of the Listed Patent and any employees and assistants under the control of such consultant or expert.

B. **Materials Accessible by Authorized Evaluators:** A copy of the ANDA, redacted to remove information of no relevance to any issue of patent infringement, will be provided for use by Authorized Evaluators.

C. **Use of the ANDA and Information in the ANDA:**

(1) The ANDA and all information contained therein or derived therefrom may be used for the sole and limited purpose of evaluating possible infringement of the Listed Patent and for no other purpose.

(2) Authorized Evaluators shall not disclose any information contained in or derived from the ANDA or any notes, analyses, studies or other documents to the extent that they reflect any information in the ANDA, to any person other than person entitled to access under subsection A.

(3) Notwithstanding the provisions of subsections 2(C)(1) and 2(C)(2) above, Authorized Evaluators shall be permitted to advise Recipients whether or not to bring suit alleging infringement of the Listed Patent; provided, however, that the information in the ANDA is not thereby disclosed.

D. **Disposition of the Information in the ANDA:**

(1) Recipients agree that if they do not file suit against Sandoz alleging infringement of the Listed Patent within forty-five (45) days of receipt of the Notice and Detailed Statement (the "45-day period"), which this offer accompanies, Recipients shall cause Authorized Evaluators within thirty (30) days after the expiration of the 45-day period, to destroy or return to Sandoz the portions of the ANDA provided, and all notes, analyses, studies or other documents to the extent that they contain information in the ANDA, and Recipients shall notify Sandoz that this has been done.

(2) Recipients agree that if any Recipient files suit against Sandoz alleging infringement of the Listed Patent within the 45-day period:

(a) While the litigation is pending, the portions of the ANDA provided and all notes, analyses, studies or other documents to the extent that they contain information in the ANDA, shall be treated as information under the highest level of confidentiality under any

protective order entered in the action brought against Sandoz. Until such a protective order is entered, subsection 2(C)(2) above continues to apply.

(b) Recipients shall cause Authorized Evaluators to destroy or return to Sandoz the portions of the ANDA provided and all notes, analyses, studies or other documents prepared to the extent that they contain information in the ANDA, within thirty (30) days after the final determination of the action brought against Sandoz.

(3) Notwithstanding the provisions of subsections 2(D)(1) and 2(D)(2) above, each outside law firm authorized to have access pursuant to subsection 2(A)(i) shall be permitted to retain one copy of the portions of the ANDA provided and each note, analysis, study or other document to the extent that they contain information in the ANDA.

E. **Accidental Disclosure**: Should information contained in the ANDA be disclosed, inadvertently or otherwise, Recipients shall, at their earliest opportunity, by and through Authorized Evaluators, contact Sandoz and identify:

(1) what has been disclosed;

(2) the individuals to whom such information has been disclosed; and

(3) steps taken by Recipients and Authorized Evaluators to ensure the information in the ANDA is not further disseminated.

3. Recipients acknowledge that violation of any provision of this Offer will cause irreparable injury to Sandoz, and that an adequate legal remedy does not exist. Sandoz, therefore, shall have the right, in addition to any other remedies available at law or in equity, to obtain from a court of competent jurisdiction an injunction to prohibit Recipients from violating the terms of this Offer. Recipients agree that in such an action Sandoz is entitled to recover any and all damages, costs and expenses, including, but not limited to, all reasonable attorneys' fees, professional fees and court costs.

4. Should any provision set forth in this Offer be found by a court of competent jurisdiction to be illegal, unconstitutional or unenforceable, the remaining provisions shall continue in full force and effect.

5. Nothing contained herein shall be construed as a grant of any license or other right to use the information in the ANDA except for the purpose expressly stated herein.

6. When accepted by Recipients, this document shall constitute the entire agreement of the parties with respect to the subject matter herein and may not be amended or modified except in writing executed by all of the parties.

7. Recipients may request access to the ANDA by executing one copy of this Offer where indicated and returning the executed copy to Eric Pomerantz, V.P. and General Counsel, at the following address: Sandoz Inc., 506 Carnegie Center, Suite 400, Princeton, NJ 08540 within the 45-day period. Thereupon, the terms contained in this

document shall be considered an enforceable contract between Sandoz and the Recipients.

8. Recipients agree that any claims for breach of this Agreement may be brought in courts located in the State of New Jersey and consent to the jurisdiction and venue of such courts for any such claims.

SANDOZ Inc.
By its authorized agent:

Beth Brannan

Date: May 11, 2005

Recipient
By its authorized agent:

Signature: _____

Name (Print): _____

Title: _____

Company: _____

Date: _____

EXHIBIT 2

Eon Labs
The Pharmacy Drug Company

May 12, 2005

By Federal Express &
Certified Mail
Return Receipt Requested

President
Janssen Pharmaceutica N.V.
Turnhoutseweg 30
B-2340 Beerse
Belgium

Certified Mail
Return Receipt Requested

President
Janssen Pharmaceutica Inc.
1125 Trenton-Harbourton Road
Titusville, New Jersey 08560-0200
U.S.A.

Audley A. Clamporcero Jr.
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933-7003

Re: Patent Notice pursuant to Section 505(j)(2)(B)(i) and (ii)
of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)(2)(B)(i) and (ii))
and 21 C.F.R. § 314.95
Our ref: 4753-57L (Galantamine hydrobromide tablets (REMINYL®))

Dear Sir or Madam:

The referenced Notice is hereby provided to Janssen Pharmaceutica N.V., the owner of U.S. Patent Nos. 6,099,863 and 6,358,527, according to the records of the U.S. Patent and Trademark Office, and Janssen Pharmaceutica Inc., the holder of new drug application ("NDA") 021169, according to the records of the U.S. Food Drug Administration, as follows:

I. The Food and Drug Administration ("FDA") has received an Abbreviated New Drug Application ("ANDA") from Eon Labs Manufacturing, Inc. ("Eon") containing bioavailability or bioequivalence data from

studies on the galantamine hydrobromide 4, 8, and 12 mg tablets which are the subject of NDA 021169 (REMINYL®). The ANDA has been submitted under 21 U.S.C. § 355(j) for the galantamine hydrobromide 4, 8, and 12 mg tablets to obtain approval to engage in the commercial manufacture, use or sale and/or importation of the galantamine hydrobromide 4, 8, and 12 mg tablets before the expiration of U.S. Patent Nos. 6,099,863 and 6,358,527.

II. The ANDA has been given No. 77-607.

III. The established name of the proposed drug product is galantamine hydrobromide, 4, 8, and 12 mg, respectively.

IV. The proposed drug product is tablets containing galantamine hydrobromide equivalent to 4, 8, and 12 mg of galantamine strength per dosage unit.

V. Eon alleges and has certified to the FDA the noninfringement of U.S. Patent Nos. 6,099,863 expiring June 6, 2017 and 6,358,527 expiring June 6, 2017, which were identified to the FDA in NDA No. 021169.

VI. A detailed statement of the factual and legal basis for Eon's opinion that U.S. Patent Nos. 6,099,863 and 6,358,527 are not infringed is set forth below.

A. THE APPLICABLE LAW

1. Claim Construction

A patent must include a specification, which comprises a written description sufficient to enable a person of ordinary skill in the art to make and use the invention. 35 U.S.C. § 112. The specification must "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention". *Id.* Like a deed to real property, the claims define the metes and bounds of the patent grant. *Corning Glass Works v. Sumitomo Elec. U.S.P., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989).

The claims of a patent may be in independent form or dependent form. 35 U.S.C. § 112. An independent claim is a claim that does not refer to another claim. A dependent claim refers to one or more other claims and is read as including all of the limitations recited in the dependent claim as well as all of the limitations in each claim to which the dependent claim refers. 35 U.S.C. § 112; *Wahpeton Canvas Co., Inc. v. Frontier, Inc.*, 870 F. 2d 1546, 1553 (Fed. Cir. 1989).

Claim construction is a matter of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). " 'To ascertain the meaning of claims, we consider three sources: The claims, the specification and the prosecution history.' " *Markman, supra*, quoting, *Unique Concepts, Inc. v. Brown*, 939 F.2d 1558, 1561 (Fed. Cir. 1991). "Claims must be read in view of the specification of which they are a part," *Markman, supra*, citing, *Autogiro Co. of America v. United States*, 384 F.2d 391, 397 (Ct. Cl. 1967) and in view of the patent's prosecution history. *Markman*, 52 F.3d at 980, citing *Graham v. John Deere Co.*, 383 U.S. 1, 33 (1966). The claims are construed as one of ordinary skill in the art would have understood them at the time the invention was made. *Markman*, 52 F.3d at 979. "Words in a claim will be given their ordinary and accustomed meaning unless it appears that the inventor used them differently." *Envirotech v. Al George, Inc.*, 730 F.2d 753, 759 (Fed. Cir. 1984); *See, Intellicall, Inc. v. Phonometrics, Inc.*, 952 F.2d 1384, 1388 (Fed. Cir. 1992). "Claims must be interpreted and given the same meaning for purposes of both validity and infringement analyses." *Smithkline Diagnostics, Inc. v. Helena Laboratories Corp.*, 859 F.2d 878, 882 (Fed. Cir. 1988).

2. Literal Infringement

To infringe a U.S. patent, the accused product or process must include each and every limitation recited in at least one claim of the patent. See, e.g. *Unique Concepts, Inc. v. Brown*, 939 F.2d 1558, 1562 (Fed. Cir. 1991).

If the accused embodiment falls squarely within the language of the claim, the infringement is said to be literal. But if an accused product or process lacks even a single claim limitation, that claim is not literally infringed. See, e.g. *Graver Tank and Manufacturing Co. v. Linde Air Products Co.*, 339 U.S. 605 (1950); *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 949 (Fed. Cir. 1987), *cert. denied*, 485 U.S. 961 (1988), and 485 U.S. 1009 (1988).

3. Infringement Under The Doctrine of Equivalents

The avoidance of literal infringement does not end the infringement inquiry. Under the doctrine of equivalents a patent claim may be construed to cover an accused product or process outside the literal language of the claim. The doctrine of equivalents is applied on an element-by-element basis, not to the claim as a whole. Infringement under the doctrine of equivalents requires a determination that each element in the accused embodiment not encompassed by the literal claim language performs substantially the same function in substantially the same way to obtain substantially the same result as the corresponding limitation in the claim. *Dawn Equipment Co. v. Kentucky Farms Inc.*, 140 F.3d 1009, 1016 (Fed. Cir. 1998). The Court of Appeals for the Federal Circuit has held that the foregoing tripartite test is part of a broader inquiry addressing the substantiality of the differences between the claim limitation(s) and the allegedly equivalent element(s) in the accused embodiment. *See Hilton Davis Chemical Co. v. Warner-Jenkinson Company, Inc.*, 62 F.3d 1512, 1518 (Fed. Cir. 1995), *rev. on other grounds* 520 U.S. 17 (1997).

Equivalency must be determined in view of the prior art and the particular circumstances of the case and requires proof that there are only insubstantial differences between the element in the accused embodiment and the corresponding limitation in the claim. *Hilton Davis*, 62 F.3d. at 1520-22. Thus, satisfaction of the tripartite test may not end the infringement inquiry, *Roton Barrier Inc. v. The Stanley Works*, 79 F.3d. 1112, 1126 (Fed. Cir. 1996), and all evidence in the record relevant to the substantiality of the differences must be considered. In assessing whether the differences are substantial, an important factor is whether persons of ordinary skill in the art would have known of the interchangeability of the limitation in the claim and the corresponding structure or step in the accused embodiment. See *Hilton Davis*, 62 F.3d at 1518-1519; *Graver*, 339 U.S. at 609.

Under no circumstance does the doctrine of equivalents allow (1) the patentee to recapture claim coverage given up during prosecution, or (2) the claims to be construed as covering that which is in the prior art. *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 870 (Fed. Cir. 1985).

4. Prosecution History Estoppel

The prosecution history of a patent consists of the entire official record in the United States Patent and Trademark Office ("PTO"), including the specification with original claims, the official actions by the Examiner and the applicant's responses, including any amendments to the claims.

Arguments made during prosecution, if sufficient to evince a clear and unmistakable surrender of subject matter, may estop an applicant from recapturing that surrendered matter under the doctrine of equivalents, whether or not such arguments were required to secure allowance of the claims. *Bayer AG v. Elan Pharmaceutical Research Corp.* 212 F.3d 1241 (Fed. Cir. 2000); *Sextant Avionique v. Analog Devices, Inc.*, 172 F.3d 817, 828 (Fed. Cir. 1999)

In *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 122 S.Ct. 1831, 152 L.Ed. 2d 944, 62 U.S.P.Q.2d 1705 (2002) ("Festo"), the Supreme Court held that when a claim is narrowed during prosecution for reasons related to patentability, there is a presumption that the patentee surrendered all subject matter between the broader, original claim language and the narrower claim language added by amendment, i.e., that the doctrine of equivalents is not applicable to the narrowed limitation.

The Supreme Court in *Festo* closely circumscribed the circumstances under which the patentee may overcome the presumption of surrender. Specifically, to overcome the presumption of surrender, the patentee must show that at the time of the amendment a person of ordinary skill in the art could not have reasonably been expected to have drafted a claim that would have literally encompassed the alleged equivalent. According to *Festo* the patentee can make this showing by demonstrating at least one of the following:

(1) that the equivalent was unforeseeable at the time of the amendment (e.g., it was an after-arising equivalent);

(2) the rationale underlying the amendment bears only a tangential relation to the equivalent in question; or

(3) there was some other reason why the patentee could not reasonably have been expected to have described the equivalent.

See also *Glaxo Wellcome, Inc. v. Impax Laboratories, Inc.*, 356 F.3d 1348 (Fed. Cir. 2004)

If at least one of these three questions is answered in the affirmative, the doctrine of equivalents may still be available to the patentee, at least as to the territory between the narrowed limitation and the broader language in the original claim.

B. EON'S PROPOSED TABLET PRODUCT

Eon's proposed tablet product contains galantamine hydrobromide as the active ingredient, and lactose monohydrate, crospovidone, and magnesium stearate as the excipients. In addition, it contains a coating film. Eon's proposed product contains neither microcrystalline cellulose (MCC) itself nor a spray-dried mixture of MCC and lactose monohydrate.

C. U.S. PATENT NO. 6,099,863

Claim 1 is the only independent claim of U.S. Patent NO. 6,099,863 ("the '863 patent"). As originally filed, claim 1 read as follows:

> 1. A tablet comprising as an active ingredient a therapeutically effective amount of galantamine hydrobromide (1:1) and a pharmaceutically acceptable carrier, characterized in that said carrier comprises a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25) as a diluent, and a disintegrant.

In a first Office Action dated October 15, 1999, the Examiner rejected claim 1 and its related dependent claims 3-5 and 7-10 under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The Examiner stated that the disintegrant crospolyvidone or croscarmellose is critical or essential to the practice of the invention, but was not included in the claim(s); hence, the claims were deemed not enabled by the disclosure.

In response, claim 1 was amended as follows:

> 1. A tablet comprising as an active ingredient a therapeutically effective amount of galantamine hydrobromide (1:1) and a pharmaceutically acceptable carrier, characterized in that said carrier comprises a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25) as a diluent, and an insoluble or poorly soluble cross-linked polymer disintegrant.

Thereafter, the Examiner allowed claim 1 and other claims dependent from claim 1.

As explained in the specification of the '863 patent, both the spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25), and the insoluble or poorly soluble cross-linked polymer disintegrant, are essential ingredients (see e.g. col. 2, lines 53-67; col. 3, lines 10-35).

D. EUROPEAN PATENT APPLICATION NO. 97927159.0

European Patent Application No. 97927159.0 (the '159 application) is a counterpart European patent application of the '863 patent discussed above. A review of the prosecution history of the '159 application is instructive for an understanding of the scope of the claims of the '863 patent.

The originally filed claim 1 of the '159 application is substantially the same as the originally filed claim 1 of the '863 patent.

In a first Office Action dated July 12, 2001, the European Examiner referred to the international preliminary examination report (IPER) and rejected the claims for the same reasons set forth in the IPER, namely, on the ground that claim 1 and all its dependent claims 2-10 lacked an inventive step because it was obvious to the person skilled in the art to combine EP 0515301 or 0515302 with U.S. patent 4,693,750.

Specifically, the Examiner noted that EP 0515301 and 0515302 already describe tablets comprising galantamine hydrobromide, lactose, microcrystalline cellulose, and magnesium stearate. According to the Examiner, the subject matter of claims 1-10 differed from the references only in that the mixture of lactose and microcrystalline cellulose is spray-dried and that the ratio of lactose monohydrate to microcrystalline cellulose is 75 to 25. Therefore, the problem to be solved by the invention was to provide better tabletting.

For the solution to this problem the person skilled in the art would turn to U.S. patent 4,693,750 which describes a direct tabletting agent consisting of a spray-dried mixture of lactose and microcrystalline

cellulose in a ratio of 75 to 25 (see col. 1, lines 32 to 37, lines 50-60, col. 2, lines 21-22, 32-33, and 39-42 of the '750 patent).

Further, since crospovidone or croscaramellose are conventional disintegrants, it would have been obvious to use any of these ingredients in a tablet formulation.

In response, the applicants amended claim 1 by limiting the disintegrant to "an insoluble or poorly soluble cross-linked polymer disingtegrant", as they did during prosecution of the U.S. '863 patent. The applicants then argued:

> A person skilled in the art would have been faced with an infinity of possibilities to solve the problem of providing a galantamine tablet with reliable immediate release characteristics. Any one of the three disclosed formulations could have been chosen as a starting point, and from there the manufacturing process could have been changed, the quantities used could have been changed, or any of the ingredients could have been changed. There was no reason and no clear suggestion in the prior art for a person skilled in the art to select the spray-dried mixtures of lactose and microcrystalline cellulose (75:25) as disclosed in U.S. patent 4,693,750 in favor of any other diluent.
>
> Furthermore, it has to be observed that the mere selection [of] the spray-dried mixtures lactose and microcrystalline cellulose (75:25) as disclosed in U.S. patent 4,693,750 as a diluent does not suffice to solve the objective problem - in order to solve the problem effectively, an insoluble or poorly soluble cross-linked polymer disintegrant is required.
>
> The specification discloses tablet forms of galantamine wherein a dissolution specification [of] 80% after 30 minutes is met when such disintegrants are used together with the specified diluent, or in other words-that the objective problem is solved by the use of a particular combination of excipients not obvious from the prior art.

The Examiner was not persuaded by the above amendments and remarks, and maintained his rejection in the April 29, 2002 Office Action.

In response, applicants argued as follows:

> A person skilled in the art would have been faced with the choice amongst many good direct tabletting agents to solve the problem of providing a galantamine tablet with reliable immediate release characteristics. As a matter of fact, initially a **physical mixture** [emphasis added] of anhydrous lactose and powdered cellulose (see Example 1) and a **physical mixture** [emphasis added] of lactose monohydrate and microcrystalline cellulose (see Example 2) was used, before switching -by a stroke of luck?-to spray-dried mixture of

> lactose monohydrate and microcrystalline cellulose (75:25). At this point in time, the inventors could have chosen among other direct tabletting agents such as microcrystalline cellulose as such (available in many grades with various moisture contents, different particle sizes and densities, e.g. the Avicel PH product range manufactured and sold by FMC Biopolymer) or a mixture of microcrystalline cellulose and guar gum (available as Avicel CE-15 from the aforementioned company), or from the products sold by various other providers.
>
> There was no reason and no clear suggestion in the prior art for a person skilled in the art to select the spray-dried mixtures of lactose and microcrystalline cellulose (75:25) as disclosed in U.S. patent 4,693,750 in favor of any other diluent.

More importantly, the applicants further amended claim 1 by adding a limitation "provided that the said carrier does not comprise talc as a glidant". According to the applicants, the use of talc as a glidant actually retards the dissolution of the active ingredient (a similar statement can be found at col. 3, lines 36-46 of the '863 patent).

Reasoning that the statement "talc should not be used as a glidant/carrier because of its adverse effects on the dissolution profile" could not have been derived from the available prior art, the Examiner allowed amended claim 1 and its dependent claims 2-8 and 10. Claim 9 was the only pending claim that was rejected, because a numeric range 3% to 5% recited therein was deemed unsupported by the specification which only discloses the ranges of 3% to 8% and 4% to 7.5%. The applicants later amended claim 9 by changing the numeric range from 3% to 5% to 3% to 8%. All pending claims were then allowed.

E. U.S. PATENT NO. 6,358,527

U.S. Patent No. 6,358,527 ("the '527 patent") matured from Application No. 09/585,122 filed June 1, 2000, which is continuation of the '863 patent.

There are six (6) claims in the '527 patent. The only two independent claims 1 and 6 read:

> 1. A method of treating a disorder selected from dementia, mania or nicotine dependence in a patient in need thereof comprising administering to the patient a tablet comprising as an active ingredient a therapeutically effective amount of galanthamine hydrobromide (1:1) and a pharmaceutically acceptable carrier, wherein said carrier comprises a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25) as a diluent, and an insoluble or poorly soluble cross-linked polymer disintegrant.

6. A fast-dissolving galanthamine hydrobromide (1:1) tablet made by (i) dry blending the active ingredient, an insoluble or poorly soluble cross-linked polymer disintegrant and an optional glidant with a diluent comprising a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25); (ii) optionally mixing a lubricant with the mixture obtained in step (i); (iii) compressing the mixture obtained in step (i) or in step (ii) in the dry state into a tablet; and (iv) optionally film-coating the tablet obtained in step (iii).

F. ANALYSIS

1. The '863 Patent

Claim 1, the only independent claim of the '863 patent, requires the presence of a spray-dried mixture of lactose and MCC (75:25) as a diluent. Eon's proposed product does not comprise a spray-dried mixture of lactose and MCC. Hence, there is no literal infringement of claim 1.

The doctrine of equivalents, as noted above, is applied on an element-by-element basis, not to the claim as a whole, in further assessing the question of infringement. No ingredient in Eon's proposed product is equivalent to the required "spray-dried mixture of lactose monohydrate and MCC (75:25)" of claim 1. For example, according to the '863 patent, crospovidone is a distintegrant (see, e.g., claim 2); magnesium stearate is a lubricant (see, e.g., claim 4); galantamine hydrobromide is the active ingredient (see, e.g., claim 1); and the coating film is recited by claim 7. Hence, none of the ingredients contained in Eon's proposed product corresponds to the recited element "spray-dried mixture" of claim 1. The only remaining ingredient, lactose monohydrate, is also not equivalent to the required "spray-dried mixture of lactose and MCC (75:25)" for at least the following reasons.

As noted above, according to the patentees both the selection of the particular excipients and the combination thereof, as recited in the claims, are essential to their invention. One of the particular excipients required is the spray-dried mixture of 75 parts of lactose monohydrate and 25 parts of MCC. Therefore, the absence of MCC in Eon's proposed product does not meet the claimed requirement of the spray-dried mixture. Lactose monohydrate itself does not constitute an equivalent of the recited spray-dried mixture of lactose monohydrate and MCC.

Further, at column 2, lines 65-67, the '863 patent states that a second disintegrant and a particular diluent containing a first disintegrant are essential to the claimed composition. As also explained in the '863 patent,

an insoluble or poorly soluble cross-linked polymer such as crospovidone or croscarmellose is the second disintegrant (see col. 3, lines 28-35). MCC is the first disintegrant, whereas lactose monohydrate is a diluent (col. 3, lines 12-13). This further demonstrates that lactose monohydrate cannot be considered an equivalent of the claimed MCC of '863 patent, let alone the claimed spray-dried mixture of lactose monohydrate and MCC. Thus, it is clear that Eon's lactose monohydrate is not an equivalent of the spray-dried mixture of lactose monohydrate and MCC.

Indeed, as the patentees of the '863 patent explained to the European Examiner, while they chose to use the claimed spray-dried mixture of lactose and microcrystalline cellulose, a person skilled in the art would have been faced with a choice amongst many good direct tableting agents to solve the problem of providing a galantamine tablet with reliable immediate release characteristics. This statement is an acknowledgement by the patentees that they only intended to encompass the particular spray-dried mixture of lactose and MCC (75:25), rather than any other well-known excipients, in their claimed invention. Hence, the patentees should not now be permitted to construe the well-known excipient "lactose monohydrate", in Eon's proposed product, as an equivalent of the claimed spray-dried mixture of lactose monohydrate and MCC under the doctrine of equivalents.

Additionally, as admitted in the '863 patent, the prior art taught a galantamine formulation containing a "physical mixture" of lactose monohydrate and MCC (see, e.g., examples 1 and 2, column 2, lines 1-35). Claim 1 of the '863 patent is therefore limited to a "spray-dried mixture" of lactose monohydrate and MCC, which is a "one-body excipient" (see, e.g., U.S. Patent 4,693,750, or the description of MicroceLac™). For example, the description of MicroceLac™ issued by manufacturer Meggle reads as follows:

> MicroceLac 100 is a spray-dried compound containing 75% alpha-lactose monohydrate (Ph. Eur./ USP-NF/JP) and 25% microcrystalline cellulose (Ph.Eur./USP-NF/JP) dry matter. Both filling properties of lactose and binding capacity of MCC have been synergistically coprocessed to an one-body excipient (emphasis added) providing better tabletting performance at lower cost.

Therefore, the patentees of the '863 patent are not permitted to construe a "physical mixture" of lactose and MCC as equivalent to the "one-body excipient", i.e. the "spray-dried mixture" of lactose monohydrate and MCC, of claim 1 under the doctrine of equivalents. Lactose monohydrate itself is more different from "the

spray-dried mixture" of claim 1 than is the "physical mixture" of lactose and MCC. The patentees of the '863 patent should accordingly not be permitted to construe lactose monohydrate itself as equivalent to the "spray-dried mixture" under the doctrine of equivalents.

Based on the foregoing, it is our opinion that there is no infringement of claim 1 of the '863 patent either literally or under the doctrine of equivalents. For at least the same reasons discussed above in connection with claim 1, there is also no infringement of the remaining claims, each of which depends from claim 1, either literally or under the doctrine of equivalents.

2. The '527 Patent

The '527 patent is continuation of the '863 patent. Similar to claim 1 of the '863 patent, the only two independent claims 1 and 6 of the '527 patent both require the presence of a spray-dried mixture of lactose and MCC (75:25) as a diluent. Therefore, for at least the same reasons as discussed in connection with claim 1 of the '863 patent, there is no infringement of claim 1 or 6 of the '527 patent either literally or under the doctrine of equivalents. Likewise, the remaining claims, all of which depend from claim 1 of the '527 patent are also not infringed by Eon's proposed product either literally or under the doctrine of equivalents. Therefore, it is our opinion that there is no infringement of any claim of the '527 patent either literally or under the doctrine of equivalents.

G. CONCLUSION

For the reasons set forth above, it is our opinion that the making, using, selling, offering to sell in the United States, or importation into the United States of a galantamine product as proposed by Eon does not constitute an infringement of any claim of the '863 and the '527 patents either literally or under the doctrine of equivalents.

For any notice or service of process, as a courtesy please notify and serve Shashank Upadhye, Esq. Vice President and Counsel at Eon Labs Inc., 1999 Marcus Avenue, Lake Success, NY 11042-1013 with copies to Thomas C. Pontani, Esq. at 551 Fifth Avenue, New York, NY 10176.

Sincerely,

Jeffrey Bauer, Ph.D.
Vice President, Business Development
Eon Labs Inc.

Enc.

CERTIFICATE OF SERVICE

I hereby certify that on the 26th day of May, 2006, the attached **NOTICE OF DEPOSITION AND SUBPOENA OF SANDOZ INC. PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 45** was served upon the below-named counsel of record at the address and in the manner indicated:

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/s/ *Tiffany Geyer Lydon*

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